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PTO/SB/21 (02-04)

Approved for use through 07/31/2006. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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<b>TRANSMITTAL FORM</b> <i>(to be used for all correspondence after initial filing)</i>		Application Number	10/698,983
		Filing Date	10/31/2003
		First Named Inventor	Howard Sands
		Art Unit	1614
		Examiner Name	Not yet assigned
Total Number of Pages in This Submission	9	Attorney Docket Number	12636-304.201

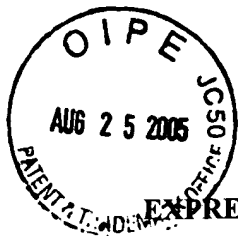
ENCLOSURES (Check all that apply)		
<input type="checkbox"/> Fee Transmittal Form <input type="checkbox"/> Fee Attached <input type="checkbox"/> Amendment/Reply <input type="checkbox"/> After Final <input type="checkbox"/> Affidavits/declaration(s) <input type="checkbox"/> Extension of Time Request <input type="checkbox"/> Express Abandonment Request <input checked="" type="checkbox"/> Information Disclosure Statement <input type="checkbox"/> Certified Copy of Priority Document(s) <input type="checkbox"/> Response to Missing Parts/Incomplete Application <input type="checkbox"/> Response to Missing Parts under 37 CFR 1.52 or 1.53	<input type="checkbox"/> Drawing(s) <input type="checkbox"/> Licensing-related Papers <input type="checkbox"/> Petition <input type="checkbox"/> Petition to Convert to a Provisional Application <input type="checkbox"/> Power of Attorney, Revocation Change of Correspondence Address <input type="checkbox"/> Terminal Disclaimer <input type="checkbox"/> Request for Refund <input type="checkbox"/> CD, Number of CD(s)	<input type="checkbox"/> After Allowance communication to Technology Center (TC) <input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences <input type="checkbox"/> Appeal Communication to TC (Appeal Notice, Brief, Reply Brief) <input type="checkbox"/> Proprietary Information <input type="checkbox"/> Status Letter <input type="checkbox"/> Other Enclosure(s) (please identify below): return receipt postcard
<b>Remarks</b>		

SIGNATURE OF APPLICANT, ATTORNEY OR AGENT	
Firm or Individual name	Shirley Chen, Reg. No. 44,608, WILSON SONSINI GOODRICH & ROSATI
Signature	<i>Shirley Chen</i>
Date	8-24-05

<b>Express Mail Date: August 25, 2005</b>
<b>Express Mail Label No.: EV518897128US</b>

This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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EXPRESS MAIL LABEL NO.: EV 518897128 US

PATENT  
Attorney Docket No. 12636-304.201

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor: Howard SANDS, et al.

Serial Number: 10/698,983

Filing Date: October 31, 2003

Title: PHARMACEUTICAL FORMULATIONS  
TARGETING SPECIFIC REGIONS OF  
THE GASTROINTESTINAL TRACT

Group Art Unit: 1614

Examiner: Not yet assigned

CONFIRMATION NO: 8849

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT**  
**UNDER 37 C.F.R. §1.97**

Sir:

Applicants hereby submit an Information Disclosure Statement along with attached form(s) PTO/SB/08A. A copy of each listed publication is being submitted, if required, pursuant to 37 C.F.R. §§1.97-1.98, as indicated below.

Applicants respectfully request that the listed information be considered by the Examiner and be made of record in the above-identified application. Applicants further request that the Examiner initial and return the attached form(s) PTO/SB/08 in accordance with MPEP §609.

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement is not intended to represent that a search has been made or that the information cited in the statement is, or is considered to be, prior art or material to patentability as defined in §1.56.

☒ 37 CFR §1.97(b). This Information Disclosure Statement should be considered by the Office because:

- ☐ (1) It is being filed within 3 months of the application filing date of a national application and is other than a continued prosecution application under §1.53(d);  
-- OR --
- ☐ (2) It is being filed within 3 months of entry of a national stage as set forth in §1.491 in an international application;  
-- OR --
- ☒ (3) It is being filed before the mailing date of the first Office Action on the merits;  
-- OR --
- ☐ (4) It is being filed before the mailing of a first Office Action after the filing of a request for continued examination under §1.114.

☐ 37 CFR §1.97(c). Although this Information Disclosure Statement is being filed after the period specified in 37 CFR §1.97(b), above, it is filed before the mailing date of the earlier of (1) a final office action under §1.113, (2) a notice of allowance under §1.311, or (3) an action that otherwise closes prosecution on the merits, this Information Disclosure Statement should be considered because it is accompanied by one of:

- ☐ a certification as specified in §1.97(e) provided concurrently herewith;  
-- OR --
- ☐ a fee of \$180.00 as set forth in §1.17(p) authorized below, enclosed, or included with the payment of other papers filed together with this statement.

☐ 37 CFR §1.97(d). Although this Information Disclosure Statement is being filed after the mailing date of the earlier of (1) a final office action under §1.113 or (2) a notice of allowance under §1.311, it is being filed before payment of the issue fee and should be considered because it is accompanied by:

- A. a certification as specified in §1.97(e); and
- B. a fee of \$180.00 as set forth in §1.17(p) is authorized below, enclosed, or included with the payment of other papers filed together with this Statement.

☐ 37 CFR §1.97(e). A certification signed by an Attorney of Record is provided herewith as required under 37 CFR §§1.97(b) and (c).

☒ 37 CFR §1.98(a)(2). The content of the Information Disclosure Statement is as follows:

- ☐ Copies of each of the references listed on the attached Form PTO/SB/08A are enclosed herewith.  
-- OR --
- ☒ Copies of U.S. Patent Documents (issued patents and patent publications) listed on the attached Form PTO/SB/08A are NOT enclosed.  
-- AND/OR --
- ☒ Copies of Foreign Patent Documents and/or Non Patent Literature Documents listed on the attached Form PTO/SB/08A are enclosed in accordance with 37 CFR §1.98(a)(2).

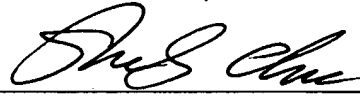
-- AND/OR --

- ☐ Copies of pending unpublished U.S. patent applications are enclosed in accordance with 37 CFR §1.98(a)(2)(iii).
- ☒ 37 CFR §1.98(a)(3). The Information Disclosure Statement includes non-English patents and/or references.
- ☒ Pursuant to 37 CFR §1.98(a)(3)(i), a concise explanation of the relevance of each patent, publication or other information provided that is not in English is provided herewith.  
DE 1922702 was published in German. The English language abstract and the drawings are sufficient to convey the scope of its disclosure.  
EP 286958 was published in German. The English language abstract and the drawings are sufficient to convey the scope of its disclosure.  
JP 05219974, JP 2002223753, JP 2002370939 and JP 2003310293 were published in Japanese. The English language abstracts are sufficient to convey the scope of their disclosure.  
WO 03/040363 was published in Japanese. The English language abstract and the drawings are sufficient to convey the scope of its disclosure.  
WO 03/046190 was published in German. The English language abstract and the drawings are sufficient to convey the scope of its disclosure.  
Should the Examiner believe that a complete translation of any of the above mentioned publications is necessary to understand their disclosure, Applicant(s) will endeavor to provide such translations at the Examiner's request.
- ☒ Pursuant to 37 CFR §1.98(a)(3)(ii), a copy of a translation of the non-English language reference(s) is provided herewith.  
CS 269077 was published in Czech. The English language translation and the drawings are sufficient to convey the scope of its disclosure.  
DE 2105468 was published in German. The English language translation and the drawings are sufficient to convey the scope of its disclosure.
- ☐ Attached are copies of search report(s) from corresponding patent application(s), submitted in accordance with MPEP 609 D in support of the attached certification under 37 CFR §1.97(e)(1).
- ☒ *Fee Authorization.* The Commissioner is hereby authorized to charge the above-referenced fees of \$0.00 and charge any additional fees or credit any overpayment associated with this communication to Deposit Account No. 23-2415 (Docket No.12636-304.201).

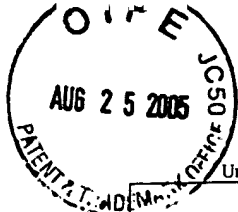
Respectfully submitted,

WILSON SONSINI GOODRICH & ROSATI

Dated: 8-24-05

By:   
Shirley Chen, Reg. No. 44,608

650 Page Mill Road  
Palo Alto, CA 94304-1050  
(650) 493-9300  
Customer No. 021971



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<b>Substitute for form 1449/PTO</b>  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> <i>(Use as many sheets as necessary)</i>				<b>Complete if Known</b>	
				Application Number	10/698,983
				Filing Date	10/31/2003
				First Named Inventor	Howard Sands
				Art Unit	1614
				Examiner Name	Not yet assigned
Sheet	1	of	5	Attorney Docket Number	12636-304.201

**U.S. PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code <sup>2</sup> (if known)			
		US-2001/0012835 A1	04/14/1997	Fine, et al.	
		US-2002/0114809 A1	02/21/2001	Rubinfeld, et al.	
		US-2002/0136709 A1	07/31/2001	Zahner	
		US-2003/0013099 A1	03/19/2001	Lasek, et al.	
		US-2003/0039689 A1	04/26/2002	Chen, et al.	
		US-2003/0045497 A1	07/26/2002	Widegren, et al.	
		US-2003/0108588 A1	09/17/2002	Chen, et al.	
		US-2003/0147813 A1	02/07/2002	Lyons	
		US-2003/0165864 A1	01/16/2002	Lasek, et al.	
		US-2003/0171303 A1	06/11/2002	Gallop, et al.	
		US-2003/0229047 A1	06/05/2002	Joshi-Hangal, et al.	
		US-4,690,918	09/01/1987	Beppu, et al.	
		US-5,736,531	12/30/1993	Von Borstel, et al.	
		US-5,856,090	09/09/1994	Epstein	
		US-5,856,094	06/30/1995	Sidransky, et al.	
		US-5,968,914	10/28/1987	Von Borstel, et al.	
		US-6,136,791	12/23/1996	Nyce	
		US-6,255,293 B1	07/24/1998	Kimchi	

Examiner Signature		Date Considered	
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup>Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup>For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup>Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>6</sup>Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND

TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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				Art Unit	1614
				Examiner Name	Not yet assigned
Sheet	2	of	5	Attorney Docket Number	12636-304.201

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>2</sup> - Number <sup>3</sup> - Kind Code <sup>4</sup> (if known)				
		CS 269077	12/22/1963	Ceskoslovenska akademie ved, (Prag)		
		DE 1922702	05/03/1969	Ceskoslovenska akademie ved, (Prag)		
		DE 2105468	02/05/1971	Ceskoslovenska akademie ved, (Prag)		
		EP 286958	04/06/1988	Merck Pg		
		JP 05219974	02/13/1992	Mitsui Petrochem Ind Ltd		
		JP 2002223753	01/30/2001	Hitachi		
		JP 2002370939	06/12/2001	Taisho Pharmaceutical Co. Ltd.		
		JP 2003310293	04/26/2002	Mitsui Chemical Inc.		
		PCT/US04/22367 International Search Report	07/20/2005	SuperGen, Inc.		
		WO 93/01202	07/05/1991	Pro-Neuron, Inc.		
		WO 94/26761	05/14/1993	Pro-Neuron, Inc.		
		WO 94/27632	06/01/1993	Nycomed Pharma A/S		
		WO 96/11280	10/07/1994	East Carolina University		
		WO 96/36693	05/19/1995	Phytera, Inc.		
		WO 96/39035	06/06/1995	Case Western Reserve University		
		WO 96/40165	06/07/1995	Pro-Neuron, Inc.		
		WO 98/14619	10/03/1996	Incyte Pharmaceuticals, Inc.		
		WO 98/16186	10/16/1996	ICN Pharmaceuticals		
		WO 98/29108	12/30/1996	Andrew, P. Feinberg		
		WO 98/54318	05/28/1997	Marie Curie Research Institute		

Examiner Signature		Date Considered	
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FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>2</sup> - Number <sup>3</sup> - Kind Code <sup>4</sup> (if known)				
		WO 00/05419	07/24/1998	Yeda Research and Development Company Ltd.		
		WO 00/23112	10/19/1998	Methylgene, Inc.		
		WO 00/40269	01/05/1999	Clarence Lee		
		WO 00/54574	03/18/1999	The University of Chicago		
		WO 00/62075	04/13/1999	Rutgers, The State University of New Jersey		
		WO 01/21215 A1	09/22/1999	Ortho-McNeil Pharmaceutical, Inc.		
		WO 01/69262 A1	03/15/2000	University of Massachusetts		
		WO 01/79164 A2	03/21/2000	Atherogenics, Inc.		
		WO 02/18592 A1	09/01/2000	Bionomics Limited		
		WO 02/21140 A1	09/08/2000	Metabolic Engineering Laboratories Co., Ltd.		
		WO 02/051980 A2	12/12/2000	Nucleus Remodeling, Inc.		
		WO 02/057425 A2	01/22/2001	Merck & Co., Inc.		
		WO 02/069903 A3	03/06/2001	Biocryst Pharmaceuticals, Inc.		
		WO 02/076486 A2	02/05/2001	Innoventus Project AB		
		WO 02/083705 A1	04/13/2001	The Johns Hopkins University School of Medicine		
		WO 02/085400 A1	04/24/2001	Supergen, Inc.		
		WO 02/087586 A1	04/26/2001	Control Delivery Systems, Inc.		
		WO 03/006950 A2	07/12/2001	Geron Corporation		

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		Country Code <sup>2</sup> - Number <sup>3</sup> - Kind Code <sup>4</sup> (if known)				
		WO 03/012112 A1	07/27/2001	Geneinvent BBL AB		
		WO 03/012085 A1	07/30/2001	Sigma-Tau Industrie Farmaceutiche Riunite S.P.A.		
		WO 03/011209 A2	07/31/2001	Yeda Research and Development Co. Ltd.		
		WO 03/026574 A2	09/24/2001	AU, Jessie, L. -S.		
		WO 03/031932 A2	10/05/2001	Case Western Reverse Univresity		
		WO 03/040363 A1	11/08/2001	Japan Science and Technology Corporation		
		WO 03/043631 A2	11/23/2001	F. Hoffman-LA Roche AG		
		WO 03/045427 A2	11/29/2001	Dandrit Biotech A/S		
		WO 03/046190 A1	11/30/2001	Medigene Aktiengesellschaft		
		WO 03/065995 A2	02/07/2002	SuperGen, Inc.		
		WO 03/076593 A2	03/07/2002	The Johns Hopkins University School of Medicine		
		WO 03/076594 A2	03/07/2002	The Johns Hopkins University		
		WO 03/086374 A1	04/05/2002	University of Utah Research Foundation		
		WO 2003/087774 A3	04/12/2002	Gurators of the University of Missouri		
		WO 03/104427 A2	06/05/2002	Case Western Reserve University		
		WO 2004/009023 A2	07/18/2002	University of Utah Research Foundation		

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